

Exhibit 1

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August 5, 2015

Via e-mail - afaes@wcllp.com

*ATTORNEY WORK PRODUCT
PRIVILEGED AND CONFIDENTIAL*

Andrew N. Faes, Esquire
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112

RE: ***In re: Ethicon, Inc. Pelvic Repair System***
Products Liability Litigation

Dear Andy:

This is in response to your July 17, 2015 letter to Christy Jones regarding Plaintiffs' particle loss 30(b)(6) deposition notice (the "Notice"), as well our telephonic meet and confer on July 22 regarding same.

As stated on the call, Defendants do not believe that Plaintiffs are entitled to a deposition on the topics described in the Notice, particularly at this stage in the litigation. Defendants continue to object to the deposition as duplicative and unnecessary because the issue of particle loss has already been addressed extensively in prior depositions. Just a basic search of the term "particle" across the company witness depositions returned close to 800 hits encompassed in approximately 25 company witnesses' depositions across 40 days of depositions. More specifically, Defendants have reviewed prior deposition notices as well as prior testimony and have determined that the overwhelming majority of the topics in the Notice have been covered either by prior testimony from multiple witnesses or Plaintiffs' prior opportunities to question company witnesses about these topics.

By way of example, Plaintiffs' counsel asked Dan Lamont, Ethicon's Post-Marketing Surveillance 30(b)(6) witness, questions about Exhibit T-3176 and the Taiwan particle loss packaging issue in his September 11, 2013 deposition.

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2 Q All right. And this is discussing
 3 just such a situation, isn't it? It's an e-mail to
 4 her saying -- discussing particles inside the
 5 packaging for the TVT product. You see that from
 6 the first sentence?

7 A Yes.

8 Q And it's a complaint related to
 9 particles inside the packaging for the TVT product
 10 in the first sentence; right?

11 A Yes.

12 Q And the next steps that are required
 13 was, one, add proof that the particles are in the
 14 package as part of the mesh, in other words, it's
 15 the mesh that's throwing off the particles; correct?

16 MR. HUTCHINSON: Object to form.

17 THE WITNESS: So the statement is
 18 demonstrate that the particles in the package are
 19 mesh particles.

Set forth below in further detail are the additional topics which we believe have already been addressed by prior testimony and/or deposition notices.

Particle Loss 30(b)(6) Topics	Prior 30(b)(6) Topics	Witness Testimony
1. All complaints and reports received by Defendants during the Relevant Time Period for TVT reporting particles or foreign material	30(b)(6) Original Design Document 485 Notice (filed 04/03/13); Topics H ¹ , U ² , V ³ , W ⁴ , X ⁵ , and AA ⁶	Lamont (09/11/13) Kammerer (01/17/14, 12/05/13, 12/03/13) Smith (08/21/13,

¹ "H. The specifics of all testing related to the TVT during the design and development stages, including but not limited to bench testing, porosity testing, particle loss, fraying, degradation, and leaching."

² "U. The monitoring, investigation and evaluation of post-marketing adverse event reports for your TVT for design issues."

³ "V. The monitoring, evaluation and utilization of unpublished and/or published medical literature regarding your TVT for design issues."

⁴ "W. As it relates to design control and validation, the investigation, evaluation and determination as to whether there is an association between the design of TVT and any adverse event experienced by patients who were provided your TVT."

⁵ "X. The investigation, evaluation and determination as to whether there is a causal connection between the design of your TVT and any adverse event or injuries."

⁶ "AA. All medical assessments of the TVT as it relates to the design control and validation process."

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Particle Loss 30(b)(6) Topics	Prior 30(b)(6) Topics	Witness Testimony
in the product or packaging.	<u>30(b)(6) Susan Lin Document 423 Notice (filed 03/04/13):</u> Topics 10 ⁷ , 11 ⁸ , and 13 ⁹ <u>30(b)(6) Document 421 Notice (filed 03/04/13):</u> Topics R ¹⁰ , S ¹¹ , T ¹² , U ¹³ , X ¹⁴ , and PP ¹⁵	08/20/13, 06/04/13) Barbolt (08/15/13, 01/08/14) Weisberg (05/31/13, 05/24/13)
2. All communication sent by Defendants to healthcare providers or received by Defendants from healthcare providers during the Relevant Time Period regarding reports of particles or foreign material in TVT packaging or product, including any communication indicating whether or not TVT products were safe to use despite particles or foreign material being present in the product or packaging.	<u>30(b)(6) Original Design Notice:</u> Topics H, U, V, W, X, and AA <u>30(b)(6) Document 421 Notice:</u> Topics R, S, T, U, X, LL ¹⁶ and PP	

⁷ “10. The processes and procedures used by Ethicon, Inc. in connection with processing TVT related adverse event reports, including the identification of policy manuals, SOPs, and safety or pharmacovigilance manuals.”

⁸ “11. The procedures for the intake, processing, handling, analyzing, investigating and reporting to the FDA and to any other U.S. governmental bodies reports of adverse events concerning your TVT products.”

⁹ “13. The processes and procedures by which a determination is made by Ethicon, Inc. as to whether an adverse event should or should not be found to be related to one of its TVT products.”

¹⁰ “R. The monitoring, investigation and evaluation of post-marketing adverse event reports for your mesh products.”

¹¹ “S. The monitoring, evaluation and utilization of unpublished and/or published medical literature regarding your mesh products.”

¹² “T. The investigation, evaluation and determination as to whether there is an association between your mesh products and any adverse event experienced by patients who were provided your mesh products.”

¹³ “U. The investigation, evaluation and determination as to whether there is a causal connection between your mesh products and any adverse event or injuries.”

¹⁴ “X. The Corrective and Preventative Action Plan (“CAPA”) relating to Ethicon, Inc.’s failure to properly maintain documents necessary for regulatory or litigation purposes.”

¹⁵ “PP. Adverse event evaluations, assessments, reporting, databases, or other expertise related to adverse events.”

¹⁶ “LL. Dear Doctor Letters – design, preparation, drafting and distribution.”

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Particle Loss 30(b)(6) Topics	Prior 30(b)(6) Topics	Witness Testimony
3. Person Most Knowledgeable regarding e-mail and attached photographs "Product Complaint CC1007005-Taiwan" (ETH.MESH.13204508-ETH.MESH.13204521) attached as Exhibit A-1.	<u>30(b)(6) Original Design Notice:</u> Topics H, U, V, W, X, and AA <u>30(b)(6) Susan Lin Document 423 Notice:</u> Topics 10, 11, and 13 <u>30(b)(6) Document 421 Notice:</u> Topics R, S, T, U, X, and PP	Lamont (09/11/13)
4. Any data relied upon to support the conclusions that the tiny mesh pieces described in Exhibit A-1 are not normal, and that Ethicon does not recommend using the TVT-O product described in Exhibit A-1, including but not limited to: any literature, complaint review, or other analyses performed by Defendants or relied upon by Defendants to support those conclusions.	Object as phrased. <u>30(b)(6) Original Design Notice:</u> Topics H, U, V, W, X, AA, BB ¹⁷ , DD ¹⁸ , and EE ¹⁹ <u>30(b)(6) Susan Lin Document 423 Notice:</u> Topics 10, 11, and 13 <u>30(b)(6) Document 421 Notice:</u> Topics R, S, T, U, X, and PP	Barbolt (01/08/14) Barbolt (08/15/13)
5. Person Most Knowledgeable regarding e-mail and attached PowerPoint Presentation "Particles in TVTO Blisters" (ETH.MESH.04101823-04101824) attached as Exhibit A-2.	<u>30(b)(6) Original Design Notice:</u> Topics H, U, V, W, X, and AA <u>30(b)(6) Susan Lin Document 423 Notice:</u> Topics 10, 11, and 13 <u>30(b)(6) Document 421 Notice:</u> Topics R, S, T, U, X, and PP	Lamont (09/11/13)
6. Any analyses performed by Defendants to determine the costs involved with any potential action to	Irrelevant.	

¹⁷ "BB. The specifics of all clinical, preclinical, and medical testing related to the TVT during the design and development stages."

¹⁸ "DD. The evaluation of data and results of any pre-clinical studies, clinical trials and testing regarding your TVT."

¹⁹ "EE. The development and coordination of any pre-clinical studies, clinical trials and design testing regarding your TVT."

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Particle Loss 30(b)(6) Topics	Prior 30(b)(6) Topics	Witness Testimony
recall or reclaim any TVT lot number(s), including any analyses performed by Defendants analyzing lost sales or lost goodwill as a result of any potential recall.		
7. Any operating procedures, standards, worksheets, or specifications used by Defendants during the Relevant Time Period for acceptance or rejection of TVT product based on particles or foreign material in the product or packaging, including but not limited to: TM403-166, EMQD10, VSE0007, C/L-E0038, and TAPPI 213/T437.	<u>30(b)(6) Original Design Notice: Topics A, D, N, and KK</u> <u>30(b)(6) Susan Lin Document 423 Notice: Topics 10, 11, and 13</u> <u>30(b)(6) Document 776 Notice (filed 08/29/13): Topic III(c-f)²⁰</u>	Dan Smith (02/04/14, 06/04/13, 02/03/14) Elbert (12/23/14)
8. Any changes during the Relevant Time Period to operating procedures, standards, worksheets, or specifications used by Defendants for acceptance or rejection of TVT product based on particles or foreign material in the product or packaging, including but not limited to: TM403-166, EMQD10, VSE0007, C/L-E0038, and TAPPI 213/T437.	<u>30(b)(6) Original Design Notice: Topics A²¹, D²², N²³, and KK²⁴</u> <u>30(b)(6) Susan Lin Document 423 Notice: Topics 10, 11, and 13</u> <u>30(b)(6) Document 776 Notice: Topic III (c-f)</u>	Smith (06/04/13, 02/04/14, 02/03/14) Elbert (12/23/14) Lamont (09/11/13)
9. Any medical analyses performed by Defendants or medical conclusions reached by Defendants regarding the appropriate operating	<u>30(b)(6) Original Design Notice: Topics H, U, V, W, X, AA, BB, DD, and EE</u>	Robinson (09/11/13) Weisberg (05/31/13) Lamont (09/11/13) Hinoul (01/13-14/14)

²⁰ "III(c-f). "Properties of the Prolene Hernia mesh and the TVT products including but not limited to the following characteristics: a. Pore size; b. Weight, c. Elasticity, d. Flexural rigidity, e. Biomechanical properties, f. Construction of knitting."

²¹ "A. The Standard Operating Procedures (SOP) associated with design and development of TVT."

²² "D. The Operating Procedures associated with Product Development Cycle."

²³ "N. Product Device Design Failure Modes Effects Analysis (dFMEA), Process Failure Modes Effects Analysis (pFMEA) and Application Failure Modes Effects Analysis (aFMEA).

²⁴ "KK. As they relate to design control and validation, the manufacturing processes, including but not limited to heating/extrusion/annealing/cooling/gamma radiation/sterilization."

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Particle Loss 30(b)(6) Topics	Prior 30(b)(6) Topics	Witness Testimony
procedures, standards, or specifications for acceptance or rejection of TVT product based on particles or foreign material in the product or packaging.	<u>30(b)(6) Susan Lin Document 423 Notice:</u> Topics 10, 11, and 13 <u>30(b)(6) Document 421 Notice:</u> Topics R, S, T, U, X, and PP	Barbolt (01/08/14) Kammerer (06/12/13 01/17/14) Divilio (10/30/14) Hart (09/18/13)
10. Person Most Knowledgeable regarding "Memo re TVT-O Particles" (ETH.MESH.04101014-04101015) attached as Exhibit A-3.	<u>30(b)(6) Original Design Notice:</u> Topics H, U, V, W, X, and AA Meng Chen already deposed.	
11. Any data relied upon by Defendants to support the conclusion that the presence of the tiny tape fragments in TVT product packages described in Exhibit A-3 is not expected to change the product safety profile of the TVT, including but not limited to: any literature, complaint review, medical analyses, or other analyses performed by Defendants or relied upon by Defendants to support that conclusion.	<u>30(b)(6) Original Design Notice:</u> Topics H, U, V, W, X, AA, BB, DD, and EE <u>30(b)(6) Susan Lin Document 423 Notice:</u> Topics 10, 11, and 13 <u>30(b)(6) Document 421 Notice:</u> Topics R, S, T, U, X, and PP	Barbolt (08/15/13, 01/08/14) Robinson (09/11/13, 07/25/13) Weisberg (05/31/13) Lamont (09/11/13) Hinoul (01/13-14/14) Kammerer (01/17/14)
12. Any data relied upon by Defendants to support the conclusion that the possibility for the tiny tape fragments to cause an adverse consequence to the patient is remote as described in Exhibit A-3, including but not limited to: any literature, complaint review, medical analyses, or other analyses performed by Defendants or relied upon by Defendants to support that conclusion.	<u>30(b)(6) Original Design Notice:</u> Topics H, U, V, W, X, AA, BB, DD, and EE <u>30(b)(6) Susan Lin Document 423 Notice:</u> Topics 10, 11, and 13 <u>30(b)(6) Document 421 Notice:</u> Topics R, S, T, U, X, and PP	Barbolt (08/15/13) Barbolt (01/08/14) Robinson (09/11/13, 07/25/13) Weisberg (05/31/13) Lamont (09/11/13) Hinoul (01/13-14/14) Barbolt (01/08/14) Kammerer (06/12/13, 01/17/14)
13. Person Most Knowledgeable regarding e-mail chain "FW: Product Complaint CC1007005-Taiwan" (ETH.MESH.01745568-01745572)	<u>30(b)(6) Original Design Notice:</u> Topics H, U, V, W, X, AA, BB, DD, and EE	Lamont (09/11/13)

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Particle Loss 30(b)(6) Topics	Prior 30(b)(6) Topics	Witness Testimony
attached as exhibit A-4.	<u>30(b)(6) Susan Lin Document 423 Notice: Topics 10, 11, and 13</u> <u>30(b)(6) Document 421 Notice: Topics R, S, T, U, X, and PP</u>	
14. Any official letter, draft letter, or other correspondence to physicians, hospitals, or regulatory authorities to explain that the tiny pieces in TVT packaging do not pose a health risk and are safe to use as described in exhibit A-4.	<u>30(b)(6) Original Design Notice: Topics H, U, V, W, X, and AA</u> <u>30(b)(6) Document 421 Notice: Topics LL and PP</u> <u>30(b)(6) Susan Lin Document 423 Notice: Topics 9, 10, 11, 12²⁵, 13, and 15²⁶</u>	
15. Person Most Knowledgeable regarding returned TVT-O products described in e-mail chain "FW: Product Complaint CC1007047&CC1007048-Taiwan (TVTO:810081)" attached as exhibit A-5, (ETH.MESH.13206130-13206134) including but not limited to: any testing or analyses that was done on those products, any photographs or those products, and current location of those products, including date of disposal and reason for disposal, if applicable.	<u>30(b)(6) Original Design Notice: Topics H, U, V, W, X, AA, BB, DD, and EE</u> <u>30(b)(6) Susan Lin Document 423 Notice: Topics 10, 11, and 13</u> <u>30(b)(6) Document 421 Notice: Topics R, S, T, U, X, and PP</u>	
16. Person Most Knowledgeable regarding e-mail and attached PowerPoint "Particles in Production"	<u>30(b)(6) Original Design Notice: Topics H, U, V, W, X, AA, BB, DD, and EE</u>	

²⁵ "12. The processes and procedures by which Ethicon, Inc. receives and processes clinical trial adverse events from its trials, including the processes by which Ethicon, Inc. conducts follow-up investigations on adverse event reports from its clinical trials or post-marketing surveillance."

²⁶ "15. The existence, maintenance, and location of records of all contacts with the FDA or communications between Ethicon, Inc. and the FDA related to adverse event reports, adverse event reporting, pharmacovigilance, or postmarketing surveillance concerning the TVT products."

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Particle Loss 30(b)(6) Topics	Prior 30(b)(6) Topics	Witness Testimony
(ETH.MESH.13907354-13907355) attached as exhibit A-6.	<u>30(b)(6) Susan Lin Document 423 Notice: Topics 10, 11, and 13</u> <u>30(b)(6) Document 421 Notice: Topics R, S, T, U, X, and PP</u>	
17. Any analyses or conclusions reached by Defendants as to the cause of the increase in Prolift, TVT, TVT-O, and P1990X products that were rejected due to particles or foreign matter in March of 2010.	Object as phrased. <u>30(b)(6) Original Design Notice: Topics H, U, V, W, X, AA, BB, DD, and EE</u> <u>30(b)(6) Susan Lin Document 423 Notice: Topics 10, 11, and 13</u> <u>30(b)(6) Document 421 Notice: Topics R, S, T, U, X, and PP</u>	
18. Any corrective actions performed by Defendants to address the increase in Prolift, TVT, TVT-O, and P1990X products that were rejected due to particles or foreign matter in March of 2010.	<u>30(b)(6) Susan Lin Document 423 Notice: Topics 9, 10, 11, 12, 13, and 15</u> <u>30(b)(6) Document 421 Notice: Topic X</u> <u>30(b)(6) Original Design Notice: Topics H, U, V, W, X, and AA</u>	
19. Person Most Knowledgeable regarding "Ethicon's Procedure for Complaint Management PR-000118" (ETH.MESH.08462125-08462148) attached as exhibit A-7, including, but not limited to the applicability of litigation holds to the portion of the	<u>30(b)(6) Susan Lin Document 423 Notice: Topic 16²⁷</u>	

²⁷ "16. The process and procedures for storing, testing and/or analyzing TVT products that have been returned to Ethicon, Inc. due to complaints of malfunction or complications and the location of any and all such storage facilities."

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Particle Loss 30(b)(6) Topics	Prior 30(b)(6) Topics	Witness Testimony
policy which provides that returned complaint samples not related to reportable adverse events may be discarded upon completion of the investigation.		
20. The date(s) when Defendants began to retain rather than discard returned TVT complaint samples in response to any litigation hold(s).	<u>30(b)(6) Susan Lin Document 423 Notice: Topic 16</u>	
21. All returned TVT complaint samples currently in the possession of Defendants, including date of receipt, reason for return, lot number, and any analyses or testing performed on those samples.	<u>30(b)(6) Susan Lin Document 423 Notice: Topic 16</u>	
22. The operating procedures, schedule, and records maintained by Defendants in maintenance and cleaning of any equipment used to cut the TVT mesh during the Relevant Time Period, including the location and storage of records.	<u>30(b)(6) Original Design Notice: Topics A, D, N, and KK</u>	
23. The operating procedures, schedule, and records maintained by Defendants in maintenance and cleaning of any manufacturing areas where the TVT mesh is cut, packaged, or sterilized during the Relevant Time Period, including the location and storage of records.	<u>30(b)(6) Original Design Notice: Topics A, D, N, and KK</u>	

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As stated on the call, despite our objections, if Plaintiffs are willing to narrow the scope of the deposition, Defendants are willing to continue to meet and confer.

Sincerely,

Philip Combs

PHILIP J. COMBS

PJC/blm

cc: **Via E-Mail**
Christy Jones, Esquire
Ben Watson, Esquire
Rich Bernardo, Esquire
Paul Rosenblatt, Esquire
Renee Baggett, Esquire
Bryan Aylstock, Esquire
Rich Freese, Esquire